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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,113	02/28/2000	Frank B. Dean	MSI 100	9257

23859 7590 11/27/2001

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127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 11/27/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,113

Applicant(s)

DEAN ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 50-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of claim 1 with the added limitation of claims 4, 9, and 20, does not reasonably provide enablement for the reduction of background where the oligonucleotides is not used as a primer and where the primer with two or more template-deficient nucleotides is of sufficient length where the 3' terminus as well as the 5' terminus or the template-deficient oligonucleotides can still bind to a template sequence, be it the intended target or that of a non-target sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As presently worded, the method of claims 1-3, 5-34, and 36-49 place no restriction on just how far the template-deficient nucleotides need to be from the 5' terminus. While the claims do stipulate that the template-deficient oligonucleotides must have the template-deficient nucleotides sufficiently upstream, or 5' to the 3' terminus such that the template-capable nucleotides 3' to the template-deficient nucleotides can alone prime an amplification reaction, there is not requirement that the 5' terminus of the same oligonucleotides could not also bind to a template. With the 5' and 3' terminal sequences

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hybridizing, and with there being no upper limit on the number of template-deficient nucleotides present, the oligonucleotides may well form a hairpin loop and readily anneal to and result in the amplification of non-target sequences and thereby increase, not decrease, the amount of unwanted amplification product.

The method of claims 10 and 41, and by extension, claims 1 and 5 from which claim 10 depends, and claims 23, 32, and 36 from which claim 41 depends, require *inter alia*, the use of "nucleotides derivatized with intercalating agents." In order for one to utilize such nucleotides it would seemingly require that the nucleotide be double stranded else there would not be the double helical structure in which the intercalating agent can insert and bind. The claims are silent as to the oligonucleotides being double stranded and as such this limitation has not been read into the claims. If the oligonucleotides is first used without any intercalating agent and is only added at a later step, it is unclear as to just when and how the agent is added, how it is appropriately targeted to select nucleotides. Similar issues of operability reside with the use of biotinylated nucleotides as biotinylation in and of its self does not necessarily result in rendering the labeled nucleotide "template-deficient."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 16 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The term "near" in claims 2 and 33 (and claims 1, 23, and 32 from which they depend) is a relative term that renders the claim indefinite. The term "near" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim 16 recites the limitation "the polymerase chain reaction" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Response to argument

Applicant, in their response of 06 September 2001, hereinafter the response, assert that a *prima facie* case of non-enablement has not been presented by the Office and request that the rejection be withdrawn. Upon consideration of the teachings in the specification and the knowledge in the art as a whole, the rejection has been relaxed to one of scope of enablement. Applicant is urged to consider narrowing the scope of the claims to those embodiments adequately supported by the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 1, 2, 5, 11, 20, 21, 23, 28, 32, 36, 39, 41-44, 46 and 49 remain rejected under 35 U.S.C. 102(a) as being anticipated by Wallace et al.

See the prior Office action for the basis for the rejection.

Response to argument

At page 12 of the response it is asserted that Wallace et al., does not anticipate the claimed invention in that there is a distinguishing characteristic within that portion of the template-deficient oligonucleotides that is 3' to the template-deficient nucleotide(s) contained therein. This argument has been fully considered and has not been found persuasive for as seen in Figure 2, effective priming is achieved with only that portion of the oligonucleotide that is 3' to the template-deficient nucleotide(s). Attention is also directed to column 4, last paragraph, bridging to column 5 where the primers are disclosed as containing elements that prevent "the nucleic acid from replicating the entire sequence of the primer" (emphasis added).

For the above reasons and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claims 1, 3, 5, 11, 13-16, 19, 20, 23-25, 28-32, 34, 36, 37, and 41-43 remain rejected under 35 U.S.C. 102(e) as being anticipated by Todd et al.

See the prior Office action for the basis for the rejection.

Response to argument

At page 13, bridging to page 14 of the response applicant argues that the presence of a single nucleotide would be insufficient to enable priming of a template sequence. This argument has been fully considered and has not been found persuasive as applicant's own method, e.g.,

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each of independent claims 1, 23 and 46 place no lower limit on the number of nucleotides that must be between the template-deficient nucleotides and the 3' terminus of the template-capable nucleotides segment. It is also noted that in column 9 the sequence of a variety of other oligonucleotides is provided; Todd et al. As set forth therein, the last ribonucleotides can be found 10 bases upstream from the 3' terminus; see SEQ ID NO:4.

In view of the foregoing remarks, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson
Primary Examiner
Art Unit 1655

bls
November 18, 2001